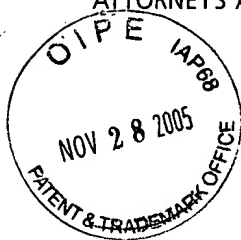


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\*Admitted only in Maryland

\*Admitted only in Virginia  
\*Practice Limited to  
Federal Agencies

93  
B1 IFW

November 28, 2005

**WRITER'S DIRECT NUMBER:**

(202) 772-8615

**INTERNET ADDRESS:**

FRANKC@SKGF.COM

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1635**

Re: U.S. Utility Patent Application  
Application No. 09/964,666; Filed: September 28, 2001  
For: **Transgenic Animals and Cell Lines for Screening Drugs Effective for  
the Treatment or Prevention of Alzheimer's Disease**

Inventors: de la MONTE *et al.*  
Our Ref: 0609.4370003/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Comments on Statement of Reasons for Allowance and Submission of Copy of Previously Filed Information Disclosure Statement Papers;
2. Copy of documents previously filed on March 12, 2002 (PTO date-stamped postcard, Cover Letter, Information Disclosure Statement, Listing of the cited documents on form PTO-1449).
3. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
November 28, 2005  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

FRC/pcd  
Enclosures

467469v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

de la MONTE *et al.*

Appl. No. 09/964,666

Filed: September 28, 2001

For: **Transgenic Animals and Cell  
Lines for Screening Drugs  
Effective for the Treatment or  
Prevention of Alzheimer's Disease**

Confirmation No.: 3650

Art Unit: 1635

Examiner: McGarry, S.

Atty. Docket: 0609.4370003/RWE/FRC

**Comments on Statement of Reasons for Allowance and Submission of  
Copy of Previously Filed Information Disclosure Statement Papers**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In reply to the "Reasons for Allowance" attached to the Notice of Allowability mailed **October 12, 2005**, Applicants submit the following comments.

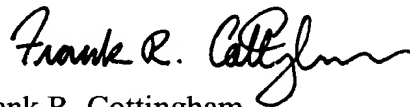
On page 3 of the Notice of Allowability, under "Reasons for Allowance," it is noted that the application file contains several references for which no corresponding PTO-1449 or IDS exists in the file. The Examiner indicated that all of the references in the IFW have been considered. The Examiner, however, recommended that the papers associated with the references, if they are "not of record due to separation from the application file in its transition from a paper file to an IFW file," be forwarded to the Office with evidence of their original filing so that they may be made of record in the application.

Applicants note that an Information Disclosure Statement, along with a Form PTO-1449 and copies of 40 cited documents, was filed on March 12, 2002. An initialed copy of the Form PTO-1449 was never provided to Applicants. It is believed that the 40 documents included with the March 12, 2002 IDS filing are the same documents referred to in the Notice of Allowability. Accordingly, Applicants submit herewith a photocopy of the IDS pleading, the Form PTO-1449 (9 sheets), the cover letter that accompanied the filing, and a date-stamped postcard acknowledging receipt of the IDS and the accompanying documents by the USPTO on March 12, 2002.

Applicants respectfully request that the Examiner indicate in the official file wrapper that the documents included in the March 12, 2002 IDS have been considered.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

Date: Nov. 28, 2005

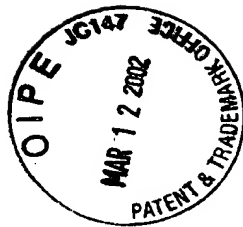
1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

Applicants: de la Monte *et al.*  
Due Date: None  
Art Unit: 1633  
Examiner: To be assigned  
Application No.: 09/964,666  
Docket: 0609.4370003  
Filed: September 28, 2001  
Atty: RWE/FRC  
For: Transgenic Animals and Cell Lines for Screening Drugs Effective for the Treatment or Prevention of Alzheimer's Disease

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

1. SKGF Cover Letter;
2. Information Disclosure Statement;
3. Listing of the cited documents on Form PTO-1449 (9 sheets);
4. A copy of each of the forty (40) cited documents on Form PTO-1449; and
5. One (1) return postcard.

Please Date Stamp And Return To Our Courier



COPY

**Sterne Kessler  
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Kenneth C. Bass III

**FILE COPY**

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March 12, 2002

Commissioner for Patents  
Washington, D.C. 20231

**INTERNET ADDRESS:**  
JGOLD@SKGF.COM

**Art Unit 1633**  
**COPY**

Re: U.S. Utility Patent Application  
Appl. No. 09/964,666; Filed: September 28, 2001  
For: **Transgenic Animals and Cell Lines for Screening Drugs  
Effective for the Treatment or Prevention of Alzheimer's  
Disease**

Inventors: de la Monte *et al.*  
Our Ref: 0609.4370003/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Listing of the cited documents on Form PTO-1449 (9 sheets);
3. A copy of each of the forty (40) cited documents on Form PTO-1449; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

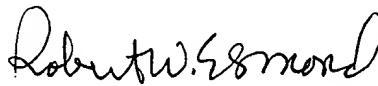
Commissioner for Patents  
March 12, 2002  
Page 2

COPY

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

RWE:FRC:dcw  
Enclosures

P:\USERS\DWRIGHT\General\ROB ESMOND\IDS-SKGF-CV-LTR-0609.4370003



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

de la Monte *et al.*

Appl. No. 09/964,666

Filed: September 28, 2001

For: **Transgenic Animals and Cell  
Lines for Screening Drugs  
Effective for the Treatment or  
Prevention of Alzheimer's Disease**

Confirmation No. 3650

Art Unit: 1633

Examiner: *To be assigned*

Atty. Docket: 0609.4370003/RWE/FRC

COPY

**Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language document AL1 cited on Form PTO 1449:

Document AL1, European Patent No. EP 0 263 740, is in the French language. An English language abstract of document AL1 is attached as document AT7.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications which are directed to related technical subject matter: U.S. Patent Application No. 09/380,203, filed April 25, 2000; U.S. Patent Application No. 09/964,678, filed September 28, 2001; U.S. Patent Application No. 09/964,412, filed September 28, 2001;



and U.S. Patent Application No. 09/964,667, filed September 28, 2001. The specifications of these applications are identical to one another, and are therefore "substantially cumulative." Accordingly, pursuant to 37 CFR § 1.98(c), a single copy of this specification is submitted herewith as document AS8. The claims currently pending from US patent application Nos. 09/380,203, 09/964,678, 09/964,412, and 09/964,667 are additionally submitted herewith as documents AT8, AR9, AS9 and AT9, respectively.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

COPY

- 3 -

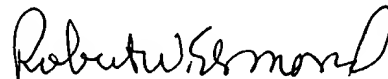
de la Monte *et al.*  
Appl. No. 09/964,666

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

Date: March 12, 2002

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COPY

Page 1 of 9

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0609.4370003/RWE/FRCAPPLICATION NO.  
09/964,666APPLICANT  
de la Monte et al.FILING DATE  
September 28, 2001GROUP  
1633

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,873,191	10/10/1989	Wagner et al.	435	172.3	08/18/1986
	AB1	5,168,053	12/01/1992	Altman et al.	435	91	08/17/1990
	AC1	5,830,670	11/03/1998	de la Monte et al.	435	7.2	05/30/1995
	AD1	5,948,634	09/07/1999	de la Monte et al.	435	69.1	11/14/1994
	AE1	5,948,888	09/07/1999	de la Monte et al.	530	350	05/30/1995
	AF1	6,071,705	06/06/2000	Wands et al.	435	7.1	06/06/1995
	AG						
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	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 263 740	04/13/1988	Europe			X Yes No
	AM1	WO 89/03849	05/05/1989	WIPO			Yes No
	AN1	WO 90/06993	06/28/1990	WIPO			Yes No
	AO1	WO 92/07065	04/30/1992	WIPO			Yes No
	AP1	WO 94/23756	10/27/1994	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Anderson, W.F., "Human gene therapy," <i>Nature</i> 392:25-30, Macmillan Journals Ltd. (April 1998).
AS	1	Bloch, D.B., et al., "Identification and Characterization of a Leukocyte-specific Component of the Nuclear Body," <i>J. Biol. Chem.</i> 271:29198-29204, The American Society for Biochemistry and Molecular Biology, Inc. (November 1996).
AT	1	Brinster, R.L., et al., "Factors affecting the efficiency of introducing foreign DNA into mice by microinjecting eggs," <i>Proc. Natl. Acad. Sci. USA</i> 82:4438-4442, National Academy of Sciences (1985).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0609.4370003/RWE/FRCAPPLICATION NO.  
09/964,666APPLICANT  
de la Monte *et al.*FILING DATE  
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1633

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	AA						
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 96/15272	05/23/1996	WIPO			Yes No
	AM2	WO 96/40895	12/19/1996	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR

2

Chiu, T.-L. and Goldstein, R.A., "Optimizing energy potentials for success in protein tertiary structure prediction," *Folding and Design* 3:223-228, Current Biology Ltd. (May 1998).

AS

2

de la Monte, S.M., *et al.*, "Enhanced Expression of an Exocrine Pancreatic Protein in Alzheimer's Disease and the Developing Human Brain," *J. Clin. Invest.* 86:1004-1013, The American Society for Clinical Investigation, Inc. (1990).

AT

2

de la Monte, S.M., *et al.*, "Regional and Maturation-associated Expression of Endothelin 2 in Rat Gastrointestinal Tract," *J. Histochem. Cytochem.* 43:203-209, The Histochemical Society, Inc. (1995).

EXAMINER

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FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR

3de la Monte, S.M., *et al.*, "Aberrant GAP-43 Gene Expression in Alzheimer's Disease," *Am. J. Pathol.* 147:934-946, American Society for Investigative Pathology (1995).

AS

3de la Monte, S.M., and Bloch, K.D., "Aberrant Expression of the Constitutive Endothelial Nitric Oxide Synthase Gene in Alzheimer Disease," *Mol. Chem. Neuropathol.* 30:139-159, Humana Press, Inc. (January/February 1997).

AT

3Games, D., *et al.*, "Alzheimer-type neuropathology in transgenic mice overexpressing V717F  $\beta$ -amyloid precursor protein," *Nature* 373:523-527, Macmillan Journals Ltd. (1995).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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Page 4 of 9

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0609.4370003/RWE/FRC	APPLICATION NO. 09/964,666
	APPLICANT de la Monte <i>et al.</i>	
	FILING DATE September 28, 2001	GROUP 1633

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>4</u>	Gossler, A., <i>et al.</i> , "Transgenesis by means of blastocyst-derived embryonic stem cell lines," <i>Proc. Natl. Acad. Sci. USA</i> 83:9065-9069, National Academy of Science (1986).
AS	<u>4</u>	Gross, J., <i>et al.</i> , "Isolation, Characterization, and Distribution of an Unusual Pancreatic Human Secretory Protein," <i>J. Clin. Invest.</i> 76:2115-2126, The American Society for Clinical Investigation, Inc. (1985).
AT	<u>4</u>	The Huntington's Disease Collaborative Research Group, "A Novel Gene Containing a Trinucleotide Repeat That Is Expanded and Unstable on Huntington's Disease Chromosomes," <i>Cell</i> 72:971-983, Cell Press (1993).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

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Page 5 of 9

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0609.4370003/RWE/FRC	APPLICATION NO. 09/964,666
	APPLICANT de la Monte <i>et al.</i>	
	FILING DATE September 28, 2001	GROUP 1633

U.S. PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>5</u>	Kosaka, K., "Dementia and Neuropathology in Lewy Body Disease," <i>Adv. Neurol.</i> 60:456-463, Raven Press, Ltd. (1993).
AS	<u>5</u>	Lannfelt, L., <i>et al.</i> , "Alzheimer's disease: molecular genetics and transgenic animal models," <i>Behav. Brain Res.</i> 57:207-213, Elsevier Science B.V. (1993).
AT	<u>5</u>	Marx, J., "Major Setback for Alzheimer's Models," <i>Science</i> 255:1200-1202, American Association for the Advancement of Science (1992).

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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Page 6 of 9

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0609.4370003/RWE/FRC	APPLICATION NO. 09/964,666
	APPLICANT de la Monte <i>et al.</i>	
	FILING DATE September 28, 2001	GROUP 1633

U.S. PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS							
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	AL						Yes
							No
	AM						Yes
							No
	AN						Yes
							No
	AO						Yes
							No
	AP						Yes
							No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>6</u>	Ozturk, M., <i>et al.</i> , "Elevated levels of an exocrine pancreatic secretory protein in Alzheimer disease brain," <i>Proc. Natl. Acad. Sci. USA</i> 86:419-423, National Academy of Sciences (1989).
AS	<u>6</u>	Pursel, V.G., <i>et al.</i> , "Genetic Engineering of Livestock," <i>Science</i> 244:1281-1288, American Association for the Advancement of Science (1989).
AT	<u>6</u>	Quon, D., <i>et al.</i> , "Formation of $\beta$ -amyloid protein deposits in brains of transgenic mice," <i>Nature</i> 352:239-241, Macmillan Journals Ltd. (1991).

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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<p>FORM PTO-1449</p> <p><u>INFORMATION DISCLOSURE STATEMENT</u></p>	<p>ATTY. DOCKET NO. 0609.4370003/RWE/FRC</p>	<p>APPLICATION NO. 09/964,666</p>
<p>APPLICANT de la Monte <i>et al.</i></p>		
<p>FILING DATE September 28, 2001</p>		<p>GROUP 1633</p>

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
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	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	Z	<p>Salter, D.W., <i>et al.</i>, "Transgenic Chickens: Insertion of Retroviral Genes into the Chicken Germ Line," <i>Virology</i> 157:236-240, Academic Press, Inc. (1987).</p>
	AS	Z	<p>Verma, I.M. and Somia, N., "Gene Therapy- promises, problems and prospects," <i>Nature</i> 389:239-242, Macmillan Journals Ltd. (September 1997).</p>
	AT	Z	<p>Dialog File 351, Accession No. 88-100135/198815, Derwent WPI English language abstract for EP 0 263 740 (Document A11).</p>

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>8</u>	International Search Report for International Application No. PCT/US98/03685, mailed July 9, 1998.	
AS	<u>8</u>	Pending Non-Provisional U.S. Patent Application No. 09/380,203, de la Monte <i>et al.</i> , filed April 25, 2000 and U.S. Patent Application Nos. 09/964,678, 09/964,412 and 09/964,667, de la Monte <i>et al.</i> , filed September 28, 2001.	
AT	<u>8</u>	Claims Currently Pending from U.S. Appl. No. 09/380,203, de la Monte <i>et al.</i> , filed April 25, 2000.	

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	2	Claims Currently Pending from U.S. Appl. No. 09/964,678, de la Monte <i>et al.</i> , filed September 28, 2001.
	AS	2	Claims Currently Pending from U.S. Appl. No. 09/964,412, de la Monte <i>et al.</i> , filed September 28, 2001.
	AT	2	Claims Currently Pending from U.S. Appl. No. 09/964,667, de la Monte <i>et al.</i> , filed September 28, 2001.

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